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7	UNITED STATES D	ISTRICT COURT				
8	DISTRICT OF NEVADA					
9	THE VACCINE CENTER LLC, d/b/a THE					
10	VACCINE CENTER AND TRAVEL MEDICINE CLINIC, a Nevada limited liability	Case No.: 2:12-cv-01849-JCM-PAL				
11	company,					
12	Plaintiff,					
13						
14	vs.					
15	GLAXOSMITHKLINE LLC, a Delaware limited					
16	liability company; APEXUS, INC., a Delaware corporation; SOUTHERN NEVADA HEALTH					
17	DISTRICT; DOES I – X and ROE					
18	CORPORATIONS I – X, inclusive,					
19	Defendants.					
20						
21	SOUTHERN NEVADA HEALTH DISTRICT'S MOTION FOR SUMMARY JUDGMENT					
22	Defendant Southern Nevada Health District, by and through its attorneys of record, Terry					
23	A. Coffing, Esq. and Christian T. Balducci, Esq., of the law firm of Marquis Aurbach Coffing,					
24	hereby file its Motion for Summary Judgment pursuant to Rule 56 of the Federal Rules of Civil					
25	Procedure and Local Rule 56-1. Defendant Southern Nevada Health District ("SNHD") requests					
26	that the Court grant summary judgment in its favor and against plaintiff, the Vaccine Center.					
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This Motion is made and based upon the pleadings and papers on file herein, the Memorandum of Points & Authorities and argument allowed by counsel at the time of hearing. In addition, SNHD hereby joins Defendants GlaxoSmithKline LLC and Apexus, Inc.'s motions for summary judgment in their entirety, including their arguments with respect to immunity as SNHD is a covered entity. SNHD also respectfully requests that this Court set this matter for oral argument.

MEMORANDUM OF POINTS AND AUTHORITIES

I. <u>INTRODUCTION</u>

The instant action is, in essence, an antitrust suit pursuant to the Robinson-Patman Act filed by Plaintiff the Vaccine Center against Defendant Apexus, Inc., a federally selected non-profit administrator ("Apexus"); Defendant GlaxoSmithKline ("GSK"), a company that sells vaccines pursuant to the federal government's Prime Vendor Program; and Defendant Southern Nevada Health District ("SNHD"), a political subdivision of the state of Nevada that is tasked and empowered with all public health matters in Clark County. The Vaccine Center, notably, is a for-profit enterprise situated within Las Vegas, Nevada, that provides vaccinations for the purpose of generating a profit from each and every individual that walks through its doors. The validity of the Vaccine Center's misplaced claims hinge upon the following question: Can a not for profit, public health organization tasked by statute with ensuring the health of individuals within Clark County be subject to antitrust liability for administering discounted vaccines to individuals within its jurisdictional territory?

The answer to this question, unequivocally, is a resounding "no." Yet, if the Vaccine Center has its way, SNHD will be subjected to treble damages for administering discounted vaccines to indigents, children, the elderly, and other individuals in Clark County. If the Vaccine Center has its way, the federal government's Prime Vendor Program will constitute a discriminatory scheme that allows local governments such as SNHD to commandeer market share from private businesses. If the Vaccine Center has its way, SNHD will be prohibited from accomplishing its mission of improving public health. Fortunately, as the answer to the question controlling this matter is "no," the Vaccine Center cannot have its way.

SNHD participates in a federal program administered by the Health Resources and Services Administration ("HRSA") entitled the 340B Drug Pricing Program ("340B Program"). The 340B Program permits covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). The 340B Program allows drug manufacturers to provide outpatient pharmaceuticals to covered entities, e.g. health departments, hospitals, community health centers, clinics, and other safety net providers, at or below the statutorily defined ceiling prices. 42 U.S.C. § 256(b).

As part of the 340B legislation, the Prime Vendor Program was created to i) to negotiate pricing on pharmaceuticals, ii) establish distribution solutions and networks that improve access to affordable medications, and iii) provide other pharmacy-related or value-added products and services. Apexus is the exclusive, national 340B Program vendor. In this capacity, Apexus negotiates substantial discounts on Program drugs for the benefit of participating covered entities, such as SNHD. While vaccines are not included as part of the 340B Program, their inclusion as "other pharmacy related products and services for covered entities" under the Prime Vendor Program furthers the overall 340B Program goal of improving access to affordable medications for covered entities and their patients. It is through the Prime Vendor Program that SNHD purchases its vaccines, a pharmacy-related or value-added product, from GSK at a discounted rate. Importantly, providing vaccines, whether to school-aged children, employees, or travelers, serves a fundamental objective of any public health agency, i.e., to prevent the spread of disease.

In acquiring and administering vaccines in this capacity, SNHD operates pursuant to and in accord with the Nonprofit Institutions Act ("NPIA"), which exempts SNHD from liability under the Robinson-Patman Act. Indeed, SNHD is exempt because the supplies and vaccines are used to further the health and inoculation of individuals within and throughout SNHD's jurisdiction to help promote "the health, the environment and well-being of Southern Nevada

¹ SNHD is a covered entity, and as such, the immunity arguments set forth in Apexus and GSK's motions equally apply to SNHD.

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residents and visitors." The supplies and vaccines, therefore, are utilized for SNHD's "own use." Such sales, accordingly, do not fall under the purview of the Robinson-Patman Act. The Vaccine Center's claims, consequently, fail as a matter of law; thus warranting summary judgment.

II. FACTUAL BACKGROUND

SNHD HEREBY INCORPORATES THE FACTUAL AND PROCEDURAL A. HISTORY SET FORTH BY GSK AND APEXUS.

Apexus, the federally selected, non-profit administrator for the congressionally created Prime Vendor Program, sets forth the history and guidelines of the program from its inception to today in its motion for summary judgment. GSK, on the other hand, sets forth the vaccines purchased by SNHD from GSK under the Prime Vendor Program, the dangers of communicable diseases that the vaccines are intended to prevent the circulation of, and provides critical background information with respect to SNHD. For the purpose of efficiency and to prevent excessive briefing, SNHD hereby incorporates the factual and procedural history set forth by Apexus and GSK in their respective motions for summary judgment herein.

В. RELEVANT, UNDISPUTED FACTS.

SNHD is a political subdivision of the state of Nevada formed pursuant to NRS 439.362 and empowered by NRS 439.366 to have jurisdiction over *all* public health matters in Clark County. SNHD's mission is to "to protect and promote the health, the environment and the wellbeing of Southern Nevada residents and visitors." See Declaration of Ms. Sorenson ¶4, attached hereto as Exhibit A. Clark County is home to more than 2 million residents, residents that SNHD serves and is empowered to protect. See Declaration of Ms. Sorenson ¶8, Exhibit A. Clark County is also home to the Las Vegas Strip, an international tourist destination that hosted 39,668,221 visitors during calendar year 2013.³ Given the large number of tourists, Clark

² See SNHD Mission Statement, available at http://www.southernnevadahealthdistrict.org/.

See the Las Vegas Convention Center States and Facts, available at http://www.lvcva.com/stats-andsee also 2013 Las Vegas Year-To-Date Executive Summary, http://www.lvcva.com/includes/content/images/media/docs/ES-YTD-2013.pdf. As both are produced by the Las Vegas Convention Authority, a source whose accuracy cannot reasonably be questioned, this

County includes a substantial work force dedicated to serving Las Vegas' domestic and international tourists. These individuals, as well as their friends, family, neighbors, and children are accordingly exposed to various infectious diseases locally, from other states, and by virtue of international travelers, diseases common and circulating within other countries. To be sure, SNHD has more than chicken pox on its plate.

Toward this end, SNHD acquires vaccines and other supplies for its "own use" under the federal government's Prime Vendor Program through Apexus from GSK. See, e.g., id. ¶¶9, 11, 13, 14. SNHD uses these vaccines to vaccinate children, the elderly, college students, travelers, and other individuals within Clark County susceptible to disease that fall within SNHD's jurisdiction. Id. Vaccination is, without any doubt, the best method to prevent the infection and proliferation of diseases, including, but not limited to, hepatitis. Id. ¶10.4 Hepatitis is a disease well known throughout Southern Nevada given the Endoscopy Center and the subsequent outbreak it caused.⁵ At the moment, it is unknown how many lives SNHD vaccinations have saved.

In furtherance of its mission, SNHD is statutorily authorized to receive federal funds, to submit to programs of the federal government and its agencies, and to enter into formal agreements with federal agencies concerning projects and programs. NRS 439.367. Entering into and acquiring vaccines and supplies through the federal government's 340B Prime Vendor Program falls squarely within SNHD's statutory authority. <u>Id.</u> The Vaccine Center, however,

Court may take judicial notice of both sources and their contents for the purpose of this motion. <u>See NRS 47.130</u>; <u>see also NRS 47.140</u>; <u>and see NRS 47.150</u>; Fed. R. Evid. 201(b) (noting that a Court shall take judicial notice if requested and supplied with the necessary information); <u>accord Doron Precision Sys., Inc. v. FAAC, Inc.</u>, 423 F. Supp. 2d 173 (S.D.N.Y. 2006) (noting courts may take judicial notice of information on a party's website); <u>Town of Southold v. Town of East Hampton</u>, 406 F. Supp. 2d 227 (E.D.N.Y. 2005). These documents are also admissible, and thus may be considered by this Court, in accord with Fed. R. Evidence 902(5) (noting that publications purporting to be published by a public authority are self-authenticating). The same holds true for each website and report referenced herein.

⁴ Referencing SNHD's Immunization Program Policy Statement, *available at* http://www.southernnevadahealthdistrictr.org/download/nursing-iz-policy-statement.pdf.

⁵ <u>See, e.g.</u>, Public Health Investigation Report, Outbreak of Hepatitis C at Outpatient Surgical Centers, *available at* http://www.southernnevadahealthdistrict.org/download/outbreaks/final-hepc-investigation-report.pdf.

seeks to punish SNHD and the companies that facilitate SNHD's ability to provide vaccinations to help accomplish its mission "to protect and promote the health, the environment and the well-being of Southern Nevada residents and visitors." As set forth, the Vaccine Center's claims are wholly misplaced as the vaccines and supplies are used for SNHD's "own use."

III. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate where no genuine issue of material fact remains and the moving party is entitled to judgment as a matter of law. FRCP 56. As to this rule, the Supreme Court has stated:

In our view, the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against the party who fails to make his showing to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof.

Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). "Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the federal rules as a whole, which are designed to 'secure the just, speedy and inexpensive determination of every action." Id. at 327. This is particular true in this matter, where the Vaccine Center has asserted claims that fail, as a matter of law, because SNHD's purchase are for its "own use," and thus, are exempt.

When considering a motion for summary judgment, the Court must perform "the threshold inquiry of determining whether there is a need for trial – whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may be reasonably be resolved in favor of either party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). As set forth, summary judgment is warranted in this matter because the Vaccine Center's claims are barred as a matter of law.

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⁶ <u>See</u> SNHD Mission Statement, *available at* http://www.southernnevadahealthdistrict.org/.

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IV. LEGAL ARGUMENT

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The Vaccine Center's action is premised upon the misconception that SNHD violated antitrust law, notably the Robinson-Patman Act (15 U.S.C. § 13(f)), in acquiring vaccinations and supplies at a reduced price from GSK through Apexus. The Vaccine Center's allegations against SNHD merely allege that "[u]nder all the circumstances, SNHD should have known that there was little likelihood of a defense for GSK under the Robinson-Patman Act or the 340B Program." See First Amended Complaint ("FAC") at pg. 13 ¶60, Dkt. #154. Flimsy allegations aside, the Vaccine Center's entire complaint fails because SNHD qualifies for the NPIA exemption set forth in 15 U.S.C. § 13c. Id. ("Nothing in the Act approved June 19, 1936, known as the Robinson-Patman Antidiscrimination Act, shall apply to purchases of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit.").

15 U.S.C. § 13c specifically exempts charitable institutions not operated for profit, such as SNHD, that purchase supplies for their own use from liability. <u>Id.</u> As set forth, the Vaccine Center's claims are barred, as a matter of law, because (A) SNHD is a charitable institution not operated for profit; (B) the vaccines are supplies within the purview of 15 U.S.C. § 13c; and (C) SNHD uses the vaccines and supplies for its "own use."

A. SNHD QUALIFIES AS A "CHARITABLE INSTITUTION" NOT OPERATED FOR PROFIT.

SNHD qualifies as a charitable institution that is not operated for profit under the NPIA. Although there is little guidance on "not for profit," SNHD meets any definition that can be ascribed. See De Modena v. Kaiser Foundation Health Plan, Inc., 743 F.2d 1388, 1391 (9th Cir. 1984); see also the Vaccine Center's Opposition to SNHD's Motion to Dismiss, Dkt. #56 (noting little, if any, opposition to SNHD's characterization as a not for profit, charitable institution). SNHD, indeed, is a public health organization created by Nevada statute. NRS 439.361 et seq. It has exclusive jurisdiction over "all public health matters in the district" in furtherance of its

mission; which critically, is to promote, protect, and preserve "the health, the environment and well-being of Southern Nevada residents and visitors."

SNHD is "dedicated to a general public purpose." See Black's Law Dictionary at pg. 240 (8th ed. 2004) (definition of "charity," which includes "dedicated to a general public purpose."). SNHD is operated exclusively for community service purposes. Id. (definition of "charitable organization," which includes operations exclusively for community services purposes.); see also Declaration of Ms. Sorenson ¶9, attached hereto as Exhibit A ("As a critical part of its mission, SNHD operates an immunization program that serves the community in and around Clark County, Nevada."). Unlike a "non-charity," such as the Vaccine Center, SNHD does not have shareholders, does not make distributions, does not reward officers or directors with bonuses or incentive pay, and does not turn a profit. See id. ¶¶14, 15. To the contrary, any incoming funds, whether by private donation or revenue from inoculations, must "be deposited with the county treasurer to the credit of the health district fund [the general fund]." NRS 439.367; accord Declaration of Ms. Sorenson ¶3, attached hereto as Exhibit A ("Any revenue is deposited into a fund designated for use by SNHD for its operations and programs.")

SNHD's general fund is to be used exclusively to fund SNHD and the work it performs throughout the community. See Declaration of Ms. Sorenson ¶3, attached hereto as Exhibit A; see also NRS 439.363. In contrast with the Vaccine Center's assertions, SNHD is not a profiteering corporation. See Declaration of Ms. Sorenson ¶15, attached hereto as Exhibit A ("No private individual or entity nor any officer or director of SNHD personally benefits or has benefitted from fees collected as part of the immunization program offered by SNHD."). Rather, SNHD is tasked with responsibility for the health and welfare of individuals within Clark County. Fees charged by SNHD are necessary and can only be utilized to defray "...the costs and expenses of the procedures...and not for the purposes of general revenue." See NRS 439.360(5).

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⁷ <u>See</u> SNHD Mission Statement, *available at* http://www.southernnevadahealthdistrict.org/.

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As such, SNHD is no different from the various, not for profit charitable institutions that the FTC has reviewed and confirmed non-profit charitable status for. See Logan Lanes v. Brunswick Corp., 378 F.2d 212, 216 (9th Cir. 1967). Taken together, it is undisputed that SNHD is a charitable institution operated not for profit under the NPIA. See, e.g., 15 U.S.C. § 13c.

B. THE VACCINES ARE SUPPLIES.

There simply can be no logical argument that vaccines are anything other than supplies within the purview of 15 U.S.C. § 13c. The HRSA's Office of Pharmacy Affairs directed the inclusion of vaccines within the 340B program as a value-added product. See, e.g., Apexus' Motion and attached evidence.⁹ Further confirming the HRSA's Office of Pharmacy Affairs is the 9th Circuit, which concluded that 15 U.S.C. § 13c uses the term "supplies" "in a more general sense. It embraces anything required to meet the institution's needs...." Logan Lanes v. Brunswick Corp., 378 F.2d 212, 216 (1967) (emphasis added), cert. denied, 389 U.S. 893 (1967); see also Abbott Laboratories v. Portland Retail Druggists Ass'n, 425 U.S. 1, 5 (1976) (noting district court ruled that purchases of pharmaceuticals were purchases of "supplies" for the hospitals' "own use."). As vaccinations are part of "anything" required to meet SNHD's obligation to promote, protect, and preserve "the health, the environment and well-being of Southern Nevada residents and visitors,"10 the conclusion that vaccinations fit squarely within the term "supplies" is inescapable. See, e.g., Declaration of Ms. Sorenson ¶10, attached hereto as **Exhibit A**. Vaccinations, accordingly, are supplies under 15 U.S.C. § 13c.

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See February 13, 2010 Community CarePartners, Inc. Advisory Opinion, attached hereto as Exhibit B (taking the fact that Community CarePartners presented itself as a non-profit at face value); February 13, 2008 Kaiser Foundation Health Plan, Inc. Advisory Opinion, attached hereto as **Exhibit C** (non-profit Kaiser Health HMO which deviated from fee-for-service and presumably held capitated rate contracts with providers and charged members monthly fee was "charitable" for purposes of the NPIA); see also April 18, 2005 Stevens Hospital Advisory Opinion, attached hereto as Exhibit D (non-profit hospital with various clinics and physician practices was "charitable" for purposes of the NPIA).

See also Department of Health and Human Services Fiscal Year 2013 Health Resources and Services Administration Justification of Estimates for Appropriations Committees at 297-98; and see Declaration of Cpt. Mitchell at pg. 7 ¶¶18–19, attached to Apexus' Motion.

¹⁰ See SNHD Mission Statement, *available at* http://www.southernnevadahealthdistrict.org/.

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C. SNHD UTILIZES THE VACCINES FOR ITS "OWN USE."

The vaccines sold by GSK to SNHD are, unquestionably, for SNHD's "own use." The United States Supreme Court provided unequivocal guidance as to the definition of "own use" in Abbott Laboratories. 425 U.S. at 14. In defining "own use" under 15 U.S.C. § 13c, the Court proclaimed "their own use' is what reasonably may be regarded as use [by the eligible institution, here SNHD] in the sense that such use is a part of and promotes [its] intended institutional operation." Id. With this in mind, the definition of "own use" focuses upon "the function performed by the institution in its purchase and resale role." The focus on function over form was confirmed by the 9th Circuit in De Modena. See De Modena, 743 F.2d at 1393.

SNHD's function is to promote, protect, and preserve "the health, the environment and well-being of Southern Nevada residents and visitors." This function, of course, is its mission statement. See Declaration of Ms. Sorenson ¶4, attached hereto as Exhibit A. Various statutes and codes confirm this function and mission. NRS 439.535, for example, requires clinics for the immunization of children "before the opening date of the school year." NRS 439.535(1). Clark County Code § 3.08.070 is unequivocal that SNHD has the power "[t]o take whatever action that is necessary to control communicable diseases." This is further confirmed by NRS 439.350(2), which requires that SNHD regulate and participate in "the prevention, suppression, and control of any contagious or infectious disease dangerous to the public health."

Vaccinations, naturally, are the most effective way to control contagious and infectious diseases "dangerous to the public health;" particularly given the domestic and international tourism in Clark County. See, e.g., Declaration of Ms. Sorenson ¶10, attached hereto as **Exhibit A**. Given the statutory mandate that SNHD exercise its exclusive jurisdiction to ensure the health of and control the spread of diseases within Clark County; there can be no dispute that each individual within the County is its constituent, its responsibility, its patient. Were it

¹¹ <u>See</u> February 13, 2008 Kaiser Foundation Health Plan, Inc. Advisory Opinion, attached hereto as **Exhibit C**.

¹² <u>See</u> SNHD Mission Statement, *available at* http://www.southernnevadahealthdistrict.org/.

¹³ <u>Id.</u>

otherwise, the legislature would not have required strict enforcement of its statute. <u>See NRS 439.550</u> (requiring health officers to strictly enforce the provisions of NRS 439 et. seq.).

As SNHD is accountable to each individual within Clark County, a populace SNHD has exclusive jurisdiction over and obligations to, inoculating individuals within the County certainly falls within SNHD's "own use." See, e.g., Declaration of Ms. Sorenson ¶10, attached hereto as Exhibit A (noting that providing vaccinations is a core public health function of SNHD, a public health authority). This parallels Kaiser's "own use" of vaccines for its insureds, to whom it was accountable for and had a "panoply" of obligations to. De Modena, 743 F.2d at 1393. It is also identical to Quest, which the FTC determined was exempt when it organized a specialty-drug cost reduction program for a group of non-profits that sought to reduce the cost of prescription medication for employees. So, just like Kaiser and Quest, SNHD serves the individuals it is directly accountable to; which here are individuals within Clark County. NRS 439.366; see also Declaration of Ms. Sorenson ¶9, attached hereto as Exhibit A (noting that SNHD serves the community throughout Southern Nevada).

Whether an individual received a vaccination at a clinic location or through a contract with a local employer at their place of business or otherwise matters not. See, e.g., id. ¶¶11–14; see also Abbott Laboratories, 425 U.S. at 9, 12 (generally noting "own use" includes a patient that receives a shot in an outpatient clinic or on hospital premises). "The term 'own use' means use by an eligible entity 'that is part of and promotes the [entity's] intended institutional operation." SNHD's intended institutional operation is to preserve health and prevent the spread of disease through Clark County. NRS 439.366; NRS 439.350(2); Clark County Code § 3.08.070. Vaccinating individuals within Clark County, undisputedly, is part of and promotes SNHD's intended institutional operation. See Declaration of Ms. Sorenson ¶10, attached hereto as Exhibit A (noting that inoculating individuals within the community is a core public

¹⁴ <u>See</u> March 7, 2014 Quest Advisory Opinion, attached hereto as **Exhibit E**.

¹⁵ <u>Id.</u> at pg. 4 § 2 (citing <u>Abbott Laboratories</u>, 425 U.S. at 16).

¹⁶ <u>Id.</u> at pg. 4 § 2 (citing <u>Abbott Laboratories</u>, 425 U.S. at 16).

health function). More to the point, the vaccinations are administered in accord with the Nevada
Legislature's mandate that SNHD "define and control dangerous communicable diseases." See
NRS 439.200(a). In all, SNHD uses the vaccines for its "own use." See, e.g. 15 U.S.C. § 13c.
SNHD, accordingly, is exempt from the Robinson-Patman Act as a charitable, not for profit
institution using supplies for its "own use."

V. CONCLUSION

SNHD's motion for summary judgment should be granted. This truly is a misplaced suit by the Vaccine Center which seeks profit over public health. This case ignores SNHD's mission, its statutory mandate, its exclusive jurisdiction, and its responsibilities to the people of Clark County. Notwithstanding the improper basis of the Vaccine Center's suit, SNHD is exempt from the Robinson-Patman Act as a charitable, not for profit institution using supplies for its own use. Unlike private, for profit companies such as the Vaccine Center, SNHD does not make distributions and is not in the business of increasing shareholder value. Rather, its purpose is to preserve and promote public health. It undisputedly qualifies as a not for profit, charitable institution.

Given the guidance provided by the 9th Circuit and HRSA, vaccines are undisputedly supplies. Last, and most importantly, SNHD utilizes the vaccines for its own use. It has a statutory obligation to preserve the health of individuals within Clark County, is required to control and prevent the spread of communicable diseases, and has exclusive jurisdiction over the County. Vaccinations administered to individuals within Clark County, consequently, are directly in accord with SNHD's institutional function. Taken together, SNHD is exempt from the Robinson-Patman Act as a charitable, not for profit institution using supplies for its "own use." Entry of summary judgment in SNHD's favor, therefore, is warranted.

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Dated this 22nd day of July, 2014.

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CERTI	FICATE	OF	SERV	VICE
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The undersigned hereby certifies that the service of the foregoing DEFENDANT SOUTHERN NEVADA HEALTH DISTRICT'S MOTION FOR SUMMARY JUDGMENT was made on the 22nd day of July, 2014, via the United States District Court's CM/ECF electronic filing system addressed to all parties on the e-service list.

> /s/Christian T. Balducci An employee of Marquis Aurbach Coffing